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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,792	01/04/2002	Anthony Krantis	ENP-001.1P US	7680

7590

04/19/2005

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/019,792	Applicant(s) KRANTIS ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 8-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/04/2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the election filed 03/04/2004.

Information Disclosure Statement

An information disclosure statement was filed on 02/03/2003. reference BE was not found, and then discovered to be a duplicate of reference BD, which had the number 923 transposed with 932. Several references were not found in the stack submitted. These references could not be considered. Specifically, these were reference BA, CX, CY, DJ and DU. These should be resubmitted with an IDS so that they may be considered.

Additionally, several references were submitted with a European Search with no accompanying information disclosure statement. An IDS listing these should be submitted so that they may be considered as part of the record.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 03/04/2004 is acknowledged. The traversal is on the ground(s) that lack of unity and a sufficient burden on this office has not been shown. This is not found persuasive because a search for all the groups would indeed entail an undue burden on this office. The methods and compositions claimed are recognized as divergent and lack an inventive

concept in that some work in directly opposing directions. For example, the search for treating obesity is not the same as the search for a method of increasing weight.

Further, Group II includes a P2xi agonist, not required in Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/04/2004.

Newly submitted claims 32-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: regulation of food intake involves another search and function to be searched. This would place an undue burden on the search capabilities of this office.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-39 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement for the term "non toxic amount" is questioned.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

An analysis of the most pertinent factors follows:

(1) The nature of the invention:

The invention provides the use of a *Fusarium* mycotoxin in the treatment of obesity. In particular, DON (also known as vomitoxin) is used in this treatment.

(2) The state of the prior art

Prior art references Coppock et al (AY), Morrissey et al (CP), and Rotter et al (DB) are cited as examples of the serious side effects encountered by digestion of this toxin.

(4) The predictability or unpredictability of the art

The unpredictability of the use of the toxin is very high. Pigs for example (especially male pigs) are more highly sensitive to the toxin than others. Predicting a safe dosage in any subject, let alone a human could not be done without undue experimentation.

(6) The amount of direction or guidance presented

The specification details the intended trichothecenes but there is no guidance as to how selection of a "non toxic dosage" is accomplished. Given the unpredictability of the effects of these toxins across species, the lack of direction as to a safe dosage range would require undue experimentation in the selection of this dosage per test subject.

(7) The presence or absence of working examples

As stated above, the specification lacks working examples showing how the dosage is selected

(8) The quantity of experimentation necessary

Given the severe side effects listed by the prior art at even small dosages, and the lack of predictable reactions across species discussed above, the amount of experimentation required to select a "nontoxic amount" of the claimed mycotoxin would place an undue burden on the ordinary practitioner in the selection of a safe dosage.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims refer to a "non toxic amount" of the claimed trichothecenes. However, these compounds, and DON in particular are Fusarium mycotoxins and are also known as vomitoxin. It is not understood how an active toxin can be used in a "non toxic amount", when it is inherently toxic at even small amounts. Articles by Coppock et al (AY), Morrissey et al (CP), and Rotter et al (DB) are cited as evidence of the serious side effects produced by this toxin at even small dosages. Applicant is requested to clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bergsjö et al (AG), further in view of Williams (DR).

Bergsjö shows that feeding pigs DON decreases body weight gain (see Abstract; page 293, last paragraph). This is equivalent to a treatment of obesity. Further, the effects of T-2 mycotoxins such as trichothecene is well known as an inherent property of that molecule. If the alternative, this property of tricothecenes on gastric motility is disclosed by Williams et al at page 374. Williams also draws an equivalence between clinical symptoms in humans, cattle, swine and bird. The Fusarium mycotoxin is listed and is inclusive of Don (see Bergsjö et al). As such the instant method is clearly anticipated by Bergsjö et al if the effects of gastric motility are viewed as an inherent property of that molecule. If in the alternative, it is not viewed as inherent, those of ordinary skill would expect similar decreases in weight as well as gastric motility effects in humans, cattle, pigs or birds given the disclosure of Bergsjö in view of Williams. The treatment of obesity and effects on gastric motility produced by administration of tricothecenes such as DON would therefore be obvious in view of the teaching of Bergsjö in view of Williams.

Claims 1-7 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arnold et al (AC) in view of Williams (DR).

Arnold et al disclose that exposure to DON causes a reduction in body weight (see Abstract; page 695, second to last paragraph). This is equivalent to a treatment of obesity. Further, the effects of T-2 mycotoxins such as trichothecene is well known as an inherent property of that molecule. If the alternative, this property of tricothecenes on gastric motility is disclosed by Williams et al at page 374. Williams also draws an equivalence between clinical symptoms in humans, cattle, swine and bird. The *Fusarium* mycotoxin is listed and is inclusive of Don (see Arnold et al). As such the instant method is clearly anticipated by Arnold et al if the effects of gastric motility are viewed as an inherent property of that molecule. If in the alternative, it is not viewed as inherent, those of ordinary skill would expect similar decreases in weight as well as gastric motility effects in humans, cattle, pigs or birds given the disclosure of Arnold et al in view of Williams. The treatment of obesity and effects on gastric motility produced by administration of tricothecenes such as DON would therefore be obvious in view of the teaching of Arnold in view of Williams.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Friend et al (BK) in view of Williams (DR).

Friend et al disclose that exposure to DON (vomitoxin) reduces weight gain in pigs (See page 773, last paragraph). This is equivalent to a treatment of obesity. Further, the effects of T-2 mycotoxins such as trichothecene is well known as an inherent property of that molecule. If the alternative, this property of tricothecenes on

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gastric motility is disclosed by Williams et al at page 374. Williams also draws an equivalence between clinical symptoms in humans, cattle, swine and bird. The Fusarium mycotoxin is listed and is inclusive of Don (see Friend et al). As such the instant method is clearly anticipated by Friend et al et al if the effects of gastric motility are viewed as an inherent property of that molecule. If in the alternative, it is not viewed as inherent, those of ordinary skill would expect similar decreases in weight as well as gastric motility effects in humans, cattle, pigs or birds given the disclosure of Friend et al in view of Williams. The treatment of obesity and effects on gastric motility produced by administration of trichothecenes such as DON would therefore be obvious in view of the teaching of Friend et al in view of Williams.

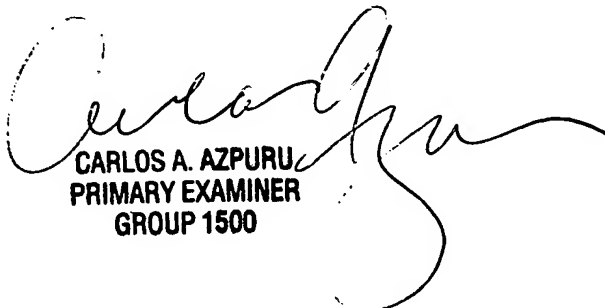
The article by D'Mello is cited for its disclosure of serious side effects caused by Fusarium mycotoxins.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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